REMARKS

Claims 1, 4-6, 9 and 10 are pending in the application. Claims 1, 4-6, 9 and 10 are rejected.

Claims 1 and 6 have been amended to recite that the protease-treated bovine serum albumin (BSA) is fragmented and consists essentially of about 2 to 10 fragments, as supported at least at page 5, lines 5-8. Claims 1 and 6 have also been amended for purposes of clarification to recite that the latex particles "carry" BSA as well as the antigen or antibody, as opposed to being directly coated with the BSA, as supported, for example, at page 13, Example 2(1) of the specification, which teaches the preparation of a second reagent that coats polystyrene particles (latex) with carbodiimide, followed by streptolysin O antigen and bovine serum albumin. Claims 1 and 6 have further been amended to clarify that the antibody or antigen on the latex particles specifically "binds to" the antigen or antibody to be assayed, as supported by the fact that an antigen-antibody reaction occurs (see, for example, page 8, second full paragraph).

No new matter is added, and entry of the amendment is requested, respectfully.

A. Claim Rejections – 35 U.S.C. § 112

1. Claims 1, 4-6 and 9-10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

a. The Examiner asserts that the description of the latex particles "being" coated with bovine serum albumin is indefinite because "being" is not a proper transitional phrase. The Examiner suggests using "comprising" or "consisting of" language.

This aspect of the rejection is overcome by amending claims 1 and 6 to recite that the latex particles "carry" the bovine serum albumin."

b. The Examiner asserts that in claim 6, the phrase "reacting" is unclear, as it does not specify the nature of the reacting. The Examiner recommends that the claim be amended to clearly indicate that the latex particle "binds" to the analyte.

Claims 1 and 6 have been amended accordingly.

2. Claims 1 and 6 (as well as dependent claims 4-5 and 9-10) are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. According to the Examiner there is no support in the specification for reciting that the latex particles are coated with BSA. The Examiner explains that the claims imply that the particles are directly coated with BSA. According to the Examiner, the disclosure page 13, Example 2(1) of the specification, cited by Applicant as support for the amendment, teaches the preparation of a second reagent that coats polystyrene particles (latex) with carbodiimide, followed by streptolysin O antigen and bovine serum albumin. Thus, the Examiner concludes that the disclosure does not support latex particles directly coated with BSA.

This rejection has been overcome by amending claims 1 and 6 to recite that the latex particles carry the BSA as they do the antigen or antibody.

B. Claim Rejections – 35 U.S.C. § 103

1. Claims 1, 4, 6, and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (U.S. Patent No. 4,096,138).

The Examiner cites Hunter et al. as teaching that antibodies and antibody fragments can be coupled to protease-treated BSA without losing the binding ability of the antibodies or antibody fragments in agglutination procedures. The Examiner cites page 361, number 2, and table IV. The Examiner admits that Hunter et al. does not teach that the protease treated BSA is fragmented. In order to compensate for this deficiency, the Examiner cites Dosa et al. as disclosing the effect of peptic degradation on the immunological and antigenic properties of BSA. The Examiner cites the abstract. According to the Examiner, Dosa et al. teaches that the BSA fragments did not form BSA-anti-BSA immune complexes and did not interact with B-cells, i.e., the fragmented BSA lost its antigenicity. The Examiner cites pages 511-512 and 516, 1st column, 1st paragraph. The Examiner further states that Dosa et al. concludes that systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of antigenic determinants on protein antigens. The Examiner cites page 515, 2nd column - discussion.

The Examiner concludes that one of ordinary skill in the art would have readily treated the BSA of Hunter et al. with protease, because Dosa et al. concludes that systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of antigenic determinants on protein antigens.

The Examiner admits that the combination of Hunter et al. and Dosa et al. does not teach the utility of BSA coated latex particles carrying an antibody or antigen specifically reactive with an analyte of interest. In order to compensate for this deficiency, the Examiner cites Scherr, According to the Examiner, Scherr teaches agglutination tests involving proteins coupled to particles, The Examiner cites column 1, lines 24-43. The Examiner further asserts that Scherr

teaches that the use of BSA coated surfaces eliminates special interference due to steric hindrance. The Examiner cites column 2, lines 38-68.

The Examiner concludes that one of ordinary skill in the art would readily use the BSA coated latex assay of Scherr with a protease pre-treatment method of Hunter et al. in order to obtain the present invention. The motivation to use the latex particles would be to reduce interferences.

The rejection is overcome and/or traversed at least because Dosa et al. does not teach that fragmented BSA consisting essentially of about 2 to 10 fragments is capable of preventing a non-specific reaction.

(1) Protease-treated fragmented BSA used in the present invention

The amended claims recite that the protease-treated fragmented BSA consists essentially of about 2 to 10 fragments. In this respect, the present specification discloses that the fragmented BSA was prepared by digesting BSA with pepsin at a ratio of 0.167 mg:500 mg (= 1:3000, pepsin:BSA) at 25°C for 30 minutes (Example 1). Under these conditions, BSA is cleaved into about 2 to 10 fragments. This protease-treated fragmented BSA consisting essentially of about 2 to 10 fragments prevents a non-specific reaction of latex particles in an immunological latex turbidimetry method (i.e., an *in vitro* system).

(2) BSA fragments digested with pepsin disclosed in Dosa et al.

As pointed out by the Examiner, Dosa et al. discloses BSA fragments digested with pepsin, and the effects of peptic degradation on the immunological and antigenic properties of BSA. Thus, Dosa et al. discloses that pretreatment of mice with BSA fragments before immunization with intact BSA resulted in significant suppression of both the primary and

secondary antibody response (see Summary). This effect of BSA fragments disclosed in Dosa et al. is known as "immunological tolerance." Immunological tolerance involves immunocytes. Thus, immunological tolerance is an effect in a living body.

With respect to the BSA fragments, Dosa et al. discloses that "(d)igestion was initiated at 25°C with pepsin at 1:650 pepsin...to albumin ratio (w/w)" (page 510, left column, lines 13-15); and that "(a)n average of ten to eleven peptide bonds per molecule were cleaved at 6 min, and thirty-four to thirty-six peptide bonds per molecule at 40 min" (page 511, left column, lines 4-6).

Furthermore, Dosa et al. discloses that "(n)o primary antibody response was induced with peptides obtained after 20 min or more of digestion" (page 513, left column, lines 3-1 from the bottom); that "the secondary total antibody response decreased when animals were immunized with peptides produced by digestion for 40 min. Peptides digested for 180 min or longer were non-immunogenic" (page 514, left column, lines 2-6); and "pre-treatment with BSA digested 12-40 min, suppressed the secondary reaginic antibody response to BSA, whereas pre-treatment with BSA digested for shorter or longer periods had no significant effect" (page 514, left column, line 3 from the bottom to page 514, right column, line 2).

It is apparent from this disclosure that the immunological suppression effects of BSA fragments observed by Dosa et al. require that the BSA be digested for at least 12 minutes with pepsin at a ratio of 1:650 (pepsin:BSA). Under these conditions, at 6 minutes BSA is cleaved into 10 to 11 fragments. This indicates that the fragments of fragmented BSA consisting of 10 to 11 fragments do not exhibit the immunological suppression effects in the living body.

Thus, Dosa et al. does not teach or suggest that protease-treated fragmented BSA consisting essentially of about 2 to 10 fragments prevents a non-specific reaction of latex particles in an immunological latex turbidimetry method.

IN fact, Dosa et al. teaches away from using protease-treated fragmented BSA consisting essentially of about 2 to 10 fragments, because Dosa et al. teaches that the BSA fragments consisting of 10 to 11 fragments do not have immunological suppression effects in the living body. Thus, one of ordinary skill in the art would not be motivated by Dosa et al. to use protease-treated fragmented BSA consisting essentially of about 2 to 10 fragments in a latex turbidimetry method.

In view of the above remarks and amendments to the claims, the Examiner is requested, respectfully, to reconsider and remove the this rejection.

2. Claims 5 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (U.S. Patent No. 4,096,138) as applied to claims 1, 4, 6, and 9 above, and further in view of Nakase et al. (JP 48019719 Abstract Only).

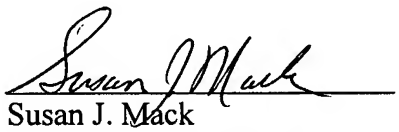
Nakase et al. is cited as teaching that BSA stabilizes streptolysin O and allows streptolysin O to maintain its activity. The Examiner concludes that one of ordinary skill in the art would substitute the streptolysin O for antigen of Scherr to thereby obtain the invention of claims 5 and 10.

This rejection is traversed and/or overcome, because Nakase et al. does not supply the deficiencies in Dosa et al., described above. Accordingly, the Examiner is requested, respectfully, to reconsider and remove this rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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Date: June 4, 2007